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(54) Title: METHOD OF CLEANSING SKIN AND IMPROVING SKIN CARE IN BAR COMPRISING SOAP, FATTY ACID AND POLYALKYLENE GLYCOL

(57) Abstract: The invention discloses a method for cleansing skin comprising washing with bars comprising predominantly fatty acid soap; free fatty acid and polyalkylene glycol wherein fatty acid to PAG are present in defined ratio and where skin condition is improved as measured by reduced skin damage as further measured by at least one of two defined tests.

METHOD OF CLEANSING SKIN AND IMPROVING SKIN CARE IN BAR
COMPRISING SOAP, FATTY ACID AND POLYALKYLENE GLYCOL

5 The invention relates to personal wash bars which are
predominantly fatty acid soap bars also comprising free
fatty acid and polyalkylene glycol. In particular, the
invention relates to method of cleansing and providing
improved skin care as measured by a reduction in barrier
10 damage or reduction in visible dryness and/or an improvement
in moisture retention relative to ordinary soap.

Consumers are increasingly interested in milder ways to
15 cleanse their skin which results in less damage of the
skin's natural protective barrier and also leads to the
retention of more moisture in their skin. Indeed toilet
bars based on synthetic surfactant such as the Dove® Beauty
Bar have gained in popularity. Also, milder synthetic based
20 liquids compositions are a growing segment of the market,
especially among consumers in the more developed markets
around the world.

However, the in-use properties of synthetic based bars
25 and liquids (syndet bars and liquids) are quite different
from soap. Synthetic based formulations tend to rinse more
slowly from the skin and often leave a feeling of a slippery
residue remaining on the skin. For many consumers in warm
tropical climates, washing with syndet bars and syndet
30 liquids is not perceived to provide the level of cleansing
and refreshing in-use sensory experience provided by soap

- 2 -

and is a less preferred method of cleansing the skin even though washing with soap is harsher. Furthermore, because of the intrinsic cost of raw materials, packaging (for liquids), and the relatively higher use-up rates, the cost
5 of cleansing with these products is expensive for most consumers in these emerging and developing markets.

There has been a great deal of research and development devoted to making soap bars milder. A recent review is
10 provided by Murahata et al. (*Cleansing Bars for Face and Body: In Search of Mildness*, in *Surfactants in Cosmetics*, Ed M. Rieger and L. Rhein, 1997 Marcel Dekker, New York). The approaches include incorporation of relatively high levels of cationic polymers, mild synthetic surfactants, and
15 the inclusion of a relatively high level of glycerol (>10%). All of these approaches have their limitations in terms of cost, manufacturing feasibility and impact on sensory properties and cost. One commercially successful approach is a so called "combo bar" made of soap and a synthetic
20 surfactant (e.g., acyl isethionate) as used for example in U.S. Patent No. 4,954,282 to Resch et al. (relating to Lever 2000® type product). Even here, the sensory properties, use-up rates and cost do not match those of soap. Thus, there is a very real need for a method of
25 cleansing the skin that is perceived to provide the refreshing cleansing experience and economy of washing with soap but which provides better skin care especially in the reduction of barrier damage and the increase in moisture retention.

30 The present invention provides a method of cleansing the skin which is perceived as effective in removing oil and

- 3 -

dirt and is preferred by consumers who like the sensory properties of soap.

The invention further provides a method of cleansing
5 the skin which provides these cleaning and preferred sensory attributes while providing improved skin care relative to washing the skin with ordinary soap. In this context "improved skin care" is defined as causing less damage to the skin's naturally protective barrier, retention of more
10 moisture in the skin, and/or reducing visible dryness than the method of cleansing the skin with an ordinary soap bar.

The invention further provides a method which provides these desirable and preferred perceived cleaning and sensory
15 properties, delivers improved skin barrier protection, reduced dryness and improved moisturization, and does so at a cost comparable with cleansing with ordinary soap.

EP Patent No. 0,707,631 to Chambers et al. discloses a
20 soap bar composition comprising:

- (a) 44 to 86.5% by wt. fatty acid soap;
- (b) 5 to 30% by wt. polyalkylene glycol;
- (c) 2.5 to 20% by wt. C₆ to C₂₂ fatty acid;
- (d) 6 to 20% by wt. water;

25

wherein ratio of polyalkylene glycol to C₆ to C₂₂ fatty acid is 1:3 to 3:1 and polyalkylene glycol has MW below 100,000 Daltons. The application fails to recognize preferred soap sensory properties while simultaneously
30 providing enhanced skin care as measured, for example, by

- 4 -

less damage to skin protective barrier and/or enhanced moisture retention relative to cleansing with ordinary soap.

Similarly, U.S. Patent No. 3,598,746 to Kaniecki
5 discloses soap, free fatty acid and polyalkylene glycol, but fails to recognize sensory properties and skin care benefits as measured in the subject invention.

Applicants have filed a continuation-in-part
10 application to the equivalent of the U.S. Chambers application noted above which also claims use of 0.1 to 50% electrolyte and providing enhanced processing benefits. This application, however, also fails to recognize enhanced sensory properties with reduced skin barrier damage and/or
15 enhanced moisture retention.

Applicants have also filed an application (filed October 13, 1998) disclosing a bar disclosing:

- (a) 50 to 80% by wt. soap;
- 20 (b) 4 to 35% by wt. free fatty acid;
- (c) 1 to 10% by wt. selected organic salts;
- (d) about 10% water;

wherein the bar has no more than about 4% synthetic and
25 is processed using standard extrusion equipment.

Unlike the subject invention, the bar does require at least some electrolyte. More importantly, as with the Chambers patents, the reference fails to recognize the soap
30 sensory properties simultaneous with reduced skin barrier

- 5 -

damage and/or moisture retention and/or reduce visible dryness.

5 The subject invention, by contrast, provides a method of cleansing skin which provides effective cleansing of dirt and oil while maintaining stronger protective barrier, or reduced visual dryness, and/or greater moisture relative to washing with soap. The method is also very economical.

10 The method of the invention comprises washing the skin with an effective amount of water and a bar comprising:

- (i) 25 to 87% by weight fatty acid soap;
- (ii) polyalkylene glycol having a MW of 400 to 25,000 Dalton;
- 15 (iii) C₈-C₂₀, preferably C₁₀-C₁₈, more preferably C₁₂-C₁₈ saturated or unsaturated fatty acid,

wherein the amount of polyalkylene glycol present in the bar must be sufficient to improve skin condition in

20 Controlled Application Wash Tests either by reducing the barrier damage as measured by transepidermal water loss, increasing skin hydration as measured by skin conductivity/capacitance, and/or by reducing visual dryness, and

25 wherein fatty acid (iii) and polyalkylene glycol (ii) are present in ratio of from 1:2 to 2:1.

- 6 -

In the drawings appended hereto:

Figure 1 shows reduced visual dryness measured by an expert grader of Bar 2 of invention (containing polyalkylene glycol and free fatty acid) versus Bar 1 without polyalkylene glycol and free fatty acid.

Figure 2 shows reduced visual dryness for Bar 4 of invention versus Bar 3.

Figure 3 shows reduced visual dryness for Bar 6 of invention versus Bar 5.

The present invention relates to a method of providing the sensory properties desirable to those users who prefer soap while maintaining the effective cleansing properties of soap (i.e., against oil and dirt) and all while causing less damage to the skin's protective barrier and/or retaining more (e.g., increasing skin hydration) moisture and/or reducing visible dryness relative to washing with soap as measured by defined tests.

The method comprises washing skin with an effective amount of water and a bar comprising: (a) fatty acid soap, (b) polyalkylene glycol; and (c) saturated or unsaturated fatty acid, wherein there is a specified ratio of fatty acid to polyalkylene glycol. When skin is washed using the specified ingredients, there has unexpectedly been found to be reduced damage to skin barrier and/or enhanced skin hydration as measured by objective instrumental measurements in Defined Controlled Application Wash Test. This is done

- 7 -

while simultaneously delivering an enhanced perception of clean skin.

Each of the ingredients of the bar is described below:

5

Fatty Acid Soaps

Bars of the invention comprise about 25% to 87%, preferably about 50% to 75% fatty acid soap.

10

The term "soap" is used herein in its popular sense, i.e., the alkali metal, alkaline earth metal or alkanol ammonium salts of aliphatic, alkane-, or alkene-monocarboxylic acids. Sodium, potassium, magnesium, mono-,
15 di- and tri-ethanol ammonium cations, or combinations thereof, are suitable for purposes of this invention. In general, sodium soaps are used in the compositions of this invention, but from about 1% to about 25% of the soap may be potassium or magnesium soaps. The soaps useful herein are
20 the well known alkali metal salts of natural or synthetic aliphatic (alkanoic or alkenoic) acids having about 8 to 22 carbon atoms, preferably about 8 to about 18 carbon atoms. They may be described as alkali metal carboxylates of acrylic hydrocarbons having about 8 to about 22 carbon
25 atoms.

Soaps having the fatty acid distribution of coconut oil may provide the lower end of the broad molecular weight range. Those soaps having the fatty acid distribution of
30 peanut or rapeseed oil, or their hydrogenated derivatives,

- 8 -

may provide the upper end of the broad molecular weight range.

It is preferred to use soaps having the fatty acid
5 distribution of coconut oil or tallow, or mixtures thereof,
since these are among the more readily available fats. The
proportion of fatty acids having at least 12 carbon atoms in
coconut oil soap is about 85%. This proportion will be
greater when mixtures of coconut oil and fats such as
10 tallow, palm oil, or non-tropical nut oils or fats are used,
wherein the principle chain lengths are C16 and higher.
Preferred soap for use in the compositions of this invention
has at least about 85% fatty acids having about 12 to 18
carbon atoms.

15

Coconut oil employed for the soap may be substituted in
whole or in part by other "high-lauric" oils, that is, oils
or fats wherein at least 50% of the total fatty acids are
composed of lauric or myristic acids and mixtures thereof.
20 These oils are generally exemplified by the tropical nut
oils of the coconut oil class. For instance, they include:
palm kernel oil, babassu oil, ouricuri oil, tucum oil,
cohune nut oil, murumuru oil, jaboty kernel oil, khakan
kernel oil, dika nut oil, and ucuhuba butter.

25

A preferred soap is a mixture of about 30% to about 40%
coconut oil and about 60% to about 70% tallow. Mixtures may
also contain higher amounts of tallow, for example, 15% to
20% coconut and 80 to 85% tallow.

30

- 9 -

The soaps may contain unsaturation in accordance with commercially acceptable standards. Excessive unsaturation is normally avoided.

- 5 Soaps may be made by the classic kettle boiling process or modern continuous soap manufacturing processes wherein natural fats and oils such as tallow or coconut oil or their equivalents are saponified with an alkali metal hydroxide using procedures well known to those skilled in the art.
- 10 Alternatively, the soaps may be made by neutralizing fatty acids, such as lauric (C12), myristic (C14), palmitic (C16), or stearic (C18) acids with an alkali metal hydroxide or carbonate.
- 15 Fatty acid soap should comprise 25 to 87% by wt., preferably 50 to 75% by wt of final bar composition.

Fatty Acid

- 20 A second required component of the invention is free fatty acid. This "superfat" traditionally would not be added in large amounts to bar compositions because it would cause bars to be tacky, suffer discoloration or have poorer lather. By tacky is meant that the bar product is sticky
- 25 and leaves a residue on the hands when the dry bar or extruded log is touched. Sticky/tacky bars stick undesirably to extrusion equipment including chamber walls and press. Generally such bars will have reduced throughput. According to the subject invention, however,
- 30 the fatty acid can be added in amounts ranging from 1% to

- 10 -

35%, preferably 4% to 30%, by wt. and most preferably 4 to 14% by wt. of the bar composition.

By free fatty acid is meant C8-C22, preferably C10-C18, 5 more preferably C12-C18, preferably saturated, straight-chain fatty acids. It should be noted that some fraction of unsaturated fatty acid may be employed.

Of course the free fatty acids can be mixtures of 10 shorter (e.g., C12-C14) and longer (e.g., C16-C18) chain fatty acids.

Polyalkylene Glycol

15 A third required component of the invention is use of polyalkylene glycol.

Polyalkylene glycols include polyethylene glycols, polypropylene, block and random copolymers of ethylene oxide 20 and propylene oxide, and their mixtures.

Another useful class of polyalkylene glycols are polyethylene glycol, especially those with MW greater or equal to 1000 that are hydrophobically modified by 25 substitution on one or more of the terminal hydroxyl groups with long chain alkyl or acyl groups.

Especially preferred polyalkylene glycols are polyethylene glycols of MW from about 300 to 25,000, 30 preferably 300 to 10,000 and more preferably 400 to 8000.

- 11 -

The fatty acid to polyalkylene glycol (PAG) ratio should be from 2:1 to 1 to 2.

The PAG should be added in an amount sufficient to
5 improve skin condition in Controlled Application Wash Test
either by reducing damage to skin barrier as measured by
Transepidermal Water Loss (TEWL) method, increasing skin
hydration as measured by skin conductivity/conductance
tests, and/or reducing visual dryness. In practice, this
10 requires a level of PAG in range of about 0.5 to 30% by wt.,
preferably 1.5 to 25% by wt., more preferably 2 to about 15%
by wt.

Optional

15

Although bars of the invention are primarily fatty acid
soap bars, some small percentage (e.g., 10% and below,
preferably 0.1-5%; it may be absent altogether) of auxiliary
surfactant may be synthetic surfactant. This includes
20 anionic surfactants, nonionic surfactants,
amphoteric/zwitterionic surfactants cationic surfactants,
etc. such as are well known to the person skilled in the
art. Among the many surfactants which may be used are those
described in U.S. Patent No. 3,723,325 to Parran Jr. et al.
25 and "Surface Active Agents and Detergents (Vol. I & II) by
Schwartz, Perry and Berch, both of which are incorporated by
reference into the subject application.

Examples of suitable anionic surfactants useful as
30 auxiliary surfactants include: alkane and alkene
sulfonates, alkyl sulfates, acyl isethionates, such as

- 12 -

sodium cocoyl isethionate, alkyl glycerol ether sulfonates, fatty amidoethanolamide sulfosuccinates, alkyl citrates, and acyl taurates, alkyl sarcosinates, and alkyl amino carboxylates. Preferred alkyl or alkenyl groups have C12-18 chain lengths.

Examples of suitable nonionic surfactants include: ethoxylates (6-25 moles ethylene oxide) of long chain (12-22 carbon atoms) alcohol (ether ethoxylates) and fatty acids (ester ethoxylates); alkyl polyhydroxy amides such as alkyl glucamides; and alkyl polyglycosides.

Examples of suitable amphoteric surfactants include simple alkyl betaines, amido betaines, especially alkyl amidopropyl betaines, sulfo betaines, and alkyl amphotoacetates.

Additives such as dyes, perfumes, soda ash, sodium chloride or other electrolyte, brighteners, etc. are normally used in an amount 0 to 3%, preferably 0.01 to 2% of the composition. Some examples are set forth below.

Perfumes; sequestering agents, such as tetrasodium ethylene diaminetetraacetate (EDTA), EHDP or mixtures in an amount of 0.01 to 1%, preferably 0.01 to 0.05%; and coloring agents, opacifiers and pearlizers such as zinc stearate, magnesium stearate, TiO₂, EGMS (ethylene glycol monostearate) or Lytron 621 (Styrene/Acrylate copolymer); all of which are useful in enhancing the appearance or cosmetic properties of the product.

- 13 -

The bar may also include compatibilizing agent such as glycerol and propylene glycol.

In addition, the bar compositions of the invention may
5 include 0 to 25% by wt., preferably 1 to 25% by wt., more preferably 5 to 20% by wt. skin protection and benefit agents and/or performance enhancers optional ingredients as follows:

Further, the bar composition of the invention may
10 include 0 to 25% by weight of crystalline or amorphous aluminium hydroxide. The said aluminium hydroxide can be generated in-situ by reacting fatty acids and/or non-fatty mono- or polycarboxylic acids with sodium aluminate, or can be prepared separately by reacting fatty acids and/or non-
15 fatty mono- or polycarboxylic acids with sodium aluminate and adding the reaction product to the soap.

Such optional additives may further include starches; modified starches and various water soluble polymers
20 chemically modified with hydrophobic moiety (e.g., EO-PO block copolymer).

Other optional additives may further include one or more of structurants such as soluble alkaline silicate, kaolin,
25 talc, calcium carbonate, inorganic electrolytes such as tetra sodium pyrophosphate, organic salts such as sodium citrate, sodium acetate, sodium adipate, sodium lactate and sodium glycolate.

30 Another class of optional ingredients are antimicrobials such as but not limited to the following:

- 14 -

2-hydroxy-4,2',4'- trichlorodiphenylether (DP300);
2,6-dimethyl-4-hydroxychlorobenzene (PCMX);
3,4,4'-trichlorocarbanilide (TCC);
3-trifluoromethyl-4,4'-dichlorocarbanilide (TFC);
5 2,2'-dihydroxy-3,3',5,5',6'-hexachlorodiphenylmethane;
2,2'-dihydroxy-3,3',5,5'-tetrachlorodiphenylmethane;
2,2'-dihydroxy-3,3',dibromo-5,5'-dichlorodiphenylmethane;
2-hydroxy-4,4'-dichlorodiphenylether;
2-hydroxy-3,5',4-tribromodiphenylether; and
10 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)-
pyridinone (Octopirox).

Other suitable antimicrobials include:

15 Benzalkonium chloride;
Benzethonium chloride;
Carbolic acid;
Cloflucarbon (Irgasan CF3: 4,4'-dichloro-3-
(trifluoromethyl)carbanilide);
20 Chlorhexidine (CHX: 1,6-di(4'-chlorophenyl-diguanido)
hexane);
Cresylic acid;
Hexetidine (5-amino-1,3-bis(2-ethylhexyl)-5-
methylhexahydropyrimidine);
25 Iodophors;
Methylbenzethonium chloride;
Povidone-iodine;
Tetramethylthiuram disulfide (TMTD: Thiram);
Tribrominated salicylanilide.

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- 15 -

Additional antimicrobials include tea tree oil, zinc salts, any of the above noted antimicrobials and mixtures thereof.

- 5 The compositions may also comprise preservatives such as dimethyloldimethylhydantoin (Glydant XL1000), parabens, sorbic acid etc.

- 10 The compositions may also comprise coconut acyl mono- or diethanol amides as lather boosters, and strongly ionizing salts such as sodium chloride and sodium sulfate may also be used to advantage.

- 15 Antioxidants such as, for example, butylated hydroxytoluene (BHT) may be used advantageously in amounts of about 0.01% or higher if appropriate.

- 20 Cationic polymers as conditioners which may be used include Quatrisoft LM-200 Polyquaternium-24, Merquat Plus 3330 - Polyquaternium 39; and Jaguar^(R) type conditioners.

Polyethylene glycols as conditioners which may be used (in addition to the required polyalkylene glycol noted above) include:

25

Polyox	WSR-205	PEG 14M,
Polyox	WSR-N-60K	PEG 45M, or
Polyox	WSR-N-750	PEG 7M.

- 16 -

Another ingredient which may be included are exfoliant particles such as polyoxyethylene beads, walnut shells, apricot seeds, and silica.

5 Benefit Agent

The benefit agent optionals of the subject invention may be a single benefit agent component, or it may be a benefit agent compound added via a carrier into the process stream. Further the benefit agent may be a mixture of two or more compounds, one or all of which may have a beneficial aspect. In addition, the benefit agent itself may act as a carrier for other components one may wish to add to the bar composition.

15

The benefit agents can be emollients, moisturizers, anti-aging agents, skin-toning agents, skin lightening agents, sun screens etc.,

20 The preferred list of benefit agents include:

- (a) silicone oils, gums and modifications thereof such as linear and cyclic polydimethylsiloxanes; amino, alkyl alkylaryl and aryl silicone oils;
- 25 (b) fats and oils including natural fats and oils such as jojoba, soybean, rice bran, avocado, almond, olive, sunflower seed oil, borage seed oil, sesame, persic, castor, coconut, mink oils; cacao fat; beef tallow, lard; hardened oils obtained by
- 30 hydrogenating the aforementioned oils; and synthetic mono, di and triglycerides such as

- 17 -

- myristic acid glyceride and 2-ethylhexanoic acid glyceride;
- (c) waxes such as carnauba, spermaceti, beeswax, lanolin and derivatives thereof;
- 5 (d) hydrophobic or hydrophilic plant extracts;
- (e) hydrocarbons such as liquid paraffins, petrolatum/vaseline, microcrystalline wax, ceresin, squalene, pristan, paraffin wax and mineral oil;
- 10 (f) additional higher fatty acids such as behenic, oleic, linoleic, linolenic, lanolic, isostearic and poly unsaturated fatty acids (PUFA);
- (g) higher alcohols such as lauryl, cetyl, stearyl, oleyl, behenyl, cholesterol and 2-hexydecanol alcohol;
- 15 (h) esters such as cetyl octanoate, myristyl lactate, cetyl lactate, isopropyl myristate, myristyl myristate, isopropyl myristate, isopropyl palmitate, isopropyl adipate, butyl stearate, decyl oleate, cholesterol isostearate, glycerol
- 20 monostearate, glycerol distearate, glycerol tristearate, alkyl lactate, alkyl citrate and alkyl tartrate;
- (i) essential oils such as mentha, jasmine, camphor, white cedar, bitter orange peel, ryu, turpentine,
- 25 cinnamon, bergamot, citrus unshiu, calamus, pine, lavender, bay, clove, hiba, eucalyptus, lemon, starflower, thyme, peppermint, rose, sage, menthol, cineole, eugenol, citral, citronelle,
- 30 borneol, linalool, geraniol, evening primrose,

- 18 -

camphor, thymol, spirantol, penene, limonene and terpenoid oils;

(j) lipids such as cholesterol, ceramides, sucrose esters and pseudo-ceramides as described in European Patent Specification No. 556,957;

(k) vitamins such as vitamin A and E, and vitamin alkyl esters, including those vitamin C alkyl esters;

(l) sunscreens such as octyl methoxyl cinnamate (Parsol MCX), octocrylene (2-ethylhexyl 2-cyano-3,3-diphenylacrylate), octyl salicylate (2 ethylhexyl salicylate), benzophenone-3 (2-hydroxy-4-methoxy benzophenone), and avobenzene (4-tert-butyl-4'-methoxydibenzoylmethane) (these are merely illustrative);

(m) phospholipids;

(n) mixtures of any of the foregoing components; and

(o) algae or seaweed extracts.

A particularly preferred benefit agent is silicone, preferably silicones having viscosity greater than about 50,000 centipoise. One example is polydimethylsiloxane having viscosity of about 60,000 centistokes.

Another preferred benefit agent is benzyl laurate.

When the benefit agent is an oil, especially a low viscosity oil, it may be advantageous to pre-thicken it to enhance its delivery. In such cases, hydrophobic polymers of the type described in U.S. 5,817,609 to He et al may be

- 19 -

employed, which is incorporated by reference into the subject application.

The benefit agent generally comprises about 0-25% by wt. of the composition, preferably 0.1 to 20%, most preferably 0.5 to 10% by wt.

Except in the operating and comparative examples, or where otherwise explicitly indicated, all numbers in this description indicating amounts or ratios of materials or conditions or reaction, physical properties of materials and/or use are to be understood as modified by the word "about".

Where used in the specification, the term "comprising" is intended to include the presence of stated features, integers, steps, components, but not to preclude the presence or addition of one or more features, integers, steps, components or groups thereof.

20

Bar Manufacture

The bars described in this application can be prepared by a number of processes described in the literature and known in the art for the manufacture of toilet soap bars. Examples of the types of manufacturing processes available are given in the book *Soap Technology for the 1990's* (Edited by Luis Spitz , American Oil Chemist Society Champaign, Illinois. 1990). These broadly include: melt forming, extrusion/stamping, and extrusion, tempering and cutting. A preferred process is extrusion and stamping

- 20 -

because of its capability to economically produce high quality bars suitable as toilet soaps.

The following examples are intended to further
5 illustrate the invention and are not intended to limit the invention in any way.

Unless indicated otherwise, all percentages are intended to be percentages by weight.

10

Methodology

The following tests which may be used, depending on the examples, are used to measure desired properties of the
15 invention.

1. Controlled Application Wash Tests

Various clinical test methods have been developed to
20 quantify the effects of cleansers on the skin, particularly to examine their relative potential to induce irritation, skin barrier damage, and dryness. These tests generally fall into two categories: i) those which employ prolonged contact of a test solution with the skin, and ii) those that
25 utilize a controlled washing protocols which involve frequent cleanser application to simulate exaggerated use within a short time period (typically one week). Examples of the former are the occluded patch test, and the soap chamber test. Controlled washing protocols include the Flex-Wash,
30 and the Arm-Wash (using two or four test sites). Another example is the Forearm Controlled Application Test (FCAT)

- 21 -

which more closely mimics actual consumer washing regimens, as discussed by Nicoll et al (*The relative sensitivity of two arm-wash test methods for evaluating the mildness of personal washing products*, J Soc. Cosmet. Chem., **46**, 129 (1995)). The latter protocols described above simulate in-home use conditions, can differentiate between formulations and may be more predictive of the skin effects that may develop. They are also considered to be more realistic than protocols that traditionally induced high levels of erythema and dryness (M.F Lukacovic, F.E. Dunlap, S.E. Michaels, M.O. Visscher, and D.D. Watson, *Forearm Wash Test to evaluate the mildness of cleansing products*, J. Soc. Cosmet. Chem., **39**, 355-366 (1988)).

The methodology employed to evaluate the effects of the present invention on skin condition employs the Controlled Washing Tests described below. These tests utilize a combination of subjective evaluations (visual skin condition assessment by expert graders) as well as objective measures, i.e. instrumental biophysical measurements to quantitate cleanser induced changes to the skin's barrier function and skin's ability to retain moisture.

Standard Arm Wash Test

25

This test has been described in detail and validated by Sharko et al (*Arm wash evaluation with instrumental evaluation - A sensitive technique for differentiating the irritation potential of personal washing products*, J. Derm. Clin. Eval. Soc. **2**, 19 (1991)). A description of the protocol follows:

- 22 -

Subjects report to the testing facility for the conditioning phase of the study, which consists of using an assigned marketed personal washing cleanser for general use at home, up to four days prior to start of the product application phase. On Day 1 of the product application phase, a visual assessment is made to determine subject qualification. Subjects must have dryness scores ≤ 1.0 and erythema scores ≤ 0.5 , and be free of cuts and abrasions on or near the test sites to be included in the product application phase. Subjects who qualify to enter the product application phase will be instructed to discontinue the use of the conditioning product and any other skin care products on their inner forearms, with the exception of the skin cleansing test formulations that are applied during the testing visits. During the five (5) day product application phase of the study, visual assessments for dryness and erythema are conducted prior to each wash session. Wash sessions are conducted 4 times daily, approximately 1.5 hours apart for the first four (4) days. On the last day, there are two (2) wash sessions followed by a final visual evaluation three hours after the final wash. Each application consists of a one or two-minute wash. In the examples shown below, a one (1) minute application was employed. There were a total of 18 washes and 19 evaluations performed in this protocol. Instrument measurements were taken at baseline and at the last evaluation.

- 23 -

Washing Procedure:

- 1) Timer is set to designated wash time (up to two minutes)
- 2) The left test site (volar forearm) is moistened with
5 warm water (90°-100°F).
- 3) Product is dispensed, lather is generated and the timer is started.
- 4) The site is washed in a back and forth motion, one
stroke per second (a stroke is from the inner elbow to
10 the wrist and back to the inner elbow) for the
designated time.
- 5) The fingertips are re-wet at the midpoint of the wash
i.e. at 30 sec for a one minute wash.
- 6) The site is rinsed with warm running water and patted
15 dry.
- 7) The above procedure (1- 6) is repeated for the right
test site.

For Bar Products: the bar is picked up, gloved hands and
20 bar are moistened and the bar is rotated ten times to
generate the lather. A metronome may be used to guide the
subjects washing rate (60 beats/minute).

Evaluation Methods

25

Baseline visual assessments are made prior to the start
of the product application phase, and immediately before
each wash session to evaluate dryness and erythema
thereafter. Washing of a test site will be discontinued if
30 a clinical dryness or erythema score of ≥ 3.0 is reached, or
at the subject's request. If only one arm is discontinued,

- 24 -

the remaining arm will continue to be washed according to schedule. The same evaluator under conditions that are consistent throughout the study will conduct all of the visual evaluations. The 0-4 grading scale shown in Table 1 is used to assess the test sites for dryness and erythema. To maintain the evaluator's blindness to product assignment, the visual assessments will be conducted in a separate area away from the product application area.

10

TABLE 1

Grade	Erythema	<u>Dryness</u>
0	None	None
0.5	Perceptible erythema	Perceptible dryness, whiteness in lines of the skin (fine white lines)
1.0	Mild, slight erythema	Slight flaking/uplifting of flakes (patchy and/or powdered appearance).
1.5	Slight to moderate erythema	Slight to moderate flaking/uplifting flakes (uniform).
2.0	Moderate, confluent erythema	Moderate flaking/uplifting flakes, (uniform) and/or slight scaling.
2.5	Moderate to marked erythema	Moderate to severe flaking/uplifting flakes and/or moderate scaling.
3.0	Marked, prominent erythema	Severe flaking/scaling, uplifting of scales and/or slight fissuring
3.5	Deep erythema	Severe scaling/uplifting scales and/or moderate fissuring
4.0	Fiery, deep erythema	Severe scaling/uplifting scales; with severe fissuring/cracking

- 25 -

Transepidermal Water Loss (TEWL) measurements for barrier integrity are made on each test site using a Servomed Evaporimeter EP1 and/or EP2 at the beginning (baseline value), and at the end of the product application phase or
5 at the time of discontinuation (final value). Two consecutive fifteen-second readings per test site are taken for each TEWL evaluation, following a thirty-second equilibration period.

10 Skin conductance is measured using a SKICON-200 instrument, with an MT-8C probe, and/or Capacitance is measured using a Corneometer, at the beginning (baseline value), and at the end of the product application phase or
15 at the time of discontinuation (final value). These methods provide objective measures of stratum corneum hydration. Three consecutive readings per test site will be taken and averaged.

Data Analysis

20 If product application has been discontinued on a test site due to a dryness or erythema score of — 3.0 all data (clinical grades) at that evaluation for that subject are carried forward for the remaining time points. Data for
25 the discontinued sites are used such that the last acceptable reading (i.e. the last fair comparison) is used as the endpoint in the analysis. Actual data for the discontinued sites is recorded, but not included in the statistical analysis.

30

- 26 -

The dryness and erythema scales are treated as ordered categorizations; hence, nonparametric statistical methods are used. At each evaluation point, the differences in clinical grades (evaluation score subtracting the baseline score) within each product is evaluated using the Wilcoxon Signed-Rank test, Pratt-Lehmann version (Lehmann, E.L. *Nonparametrics: Statistical Methods Based on Ranks*. San Francisco, CA: Holden Day, 1975, pg.130). Statistical significance will be determined at the 90% confidence level ($p \leq 0.10$). This will indicate if the treatment results are statistically significant from their baseline score.

Means, median scores, and mean ranks across all subjects for each treatment at each evaluation point are calculated and recorded. At each evaluation point, the differences in clinical grades (evaluation-baseline) for each test product is evaluated using the Wilcoxon Signed-Rank test, Pratt-Lehmann version. This indicates if the products are statistically significantly different from each other (90% confidence level ($p \leq 0.10$)).

For the instrumental data, the same comparisons are made using parametric statistical methods. The TEWL and conductance measurements are averaged separately for each subject, site, and session. For all treatments, treatment differences are statistically compared using a paired t-test at each evaluation point. Statistical significance will be determined at the 90% confidence level ($p \leq 0.10$).

The data will also be assessed to determine whether one treatment impacts skin condition to a greater degree

- 27 -

relative to the other test cell through the number of discontinuations. For each attribute, a survival analysis will examine treatment performance over wash sessions. The analysis will incorporate the number of wash sessions
5 that a subject's treatment site is actually washed in the study. If the treatment site is discontinued, then the site's survival time is determined at that evaluation. An overlay plot of the estimated survival function for each treatment group will be examined. The Log-Rank test
10 statistic will be computed to test for homogeneity of treatment groups. This test will tell if the survival functions are the same for each of the treatment groups. Also, the number of wash sessions survived by a treatment site during the study (prior to the possible
15 discontinuation of that side) will be compared between treatments via a paired t-test, using the test subject as a block.

If dryness and erythema rank scores are also assigned
20 at each evaluation, the treatments will be compared with respect to the rank scores by application of the Friedman's test on the ranks, with subject acting as a block [ref. Hollander, Myles and Douglas A. Wolfe. *Nonparametric Statistical Methods*. New York, NY. John Wiley & Sons, 1973,
25 pp. 139-146].

At each evaluation, if Friedman's test examining treatment effects is significant at a p-value of 0.05 or other preselected level, then multiple comparison tests
30 comparing each pair of treatments will be performed. For comparison of all possible pairs of treatments, the

- 28 -

procedure documented in Hollander and Wolfe pp. 151-155 will be used. This test is based on the Friedman rank sums. For comparison of treatments vs. a control, the procedure documented in Hollander and Wolfe pp. 155-158 will be used.

5

4-Site Arm Wash Test

The 4-Site Arm Wash is very similar to the Standard Arm Wash protocol described above with the exception that each forearm is divided into two sites and the sites are typically washed for a shorter duration. In this protocol, four separate compositions can be examined and compared. The visual grading, instrumental assessments, and data analysis are the same as that described above and essentially by Sharko et al.

Washing Procedure:

- 20 1. The washing of both forearms can be conducted simultaneously.
2. Timer is set to designated wash time (up to two minutes).
3. The upper test sites (right and left forearm) are
25 moistened with warm water (90°-100°F).
4. Product is dispensed, lather is generated and the timer is started.
5. The site is washed in a back and forth motion, one stroke per second. For 4-site arm wash a stroke is
30 from the wrist to mid-arm and back to the wrist; or

- 29 -

from the mid-arm to elbow and back to the mid-arm) for the designated time (e.g. 1 minute).

6. For washes over thirty seconds, technician's hands will be re-wet after half of the total time has elapsed and washing will continue.

7. The sites are rinsed with warm running water (90-100°F) and patted dry.

8. The above procedure (1- 7) is then repeated for the lower test sites

For Bar Products: the bar is picked up, gloved hands and bar are moistened, and the bar is rotated ten times to generate the lather. A metronome may be used to guide the subjects washing rate.

Evaluation Methods

Same as the Standard Arm Wash

Data Analysis

Same as the Standard Arm Wash

Forearm Controlled Application Test (FCAT)

This controlled washing test is similar to that described by Ertel et al (A forearm controlled application technique for estimating the relative mildness of personal cleansing products, J. Soc. Cosmet. Chem., 46, 67 (1995)).

- 30 -

Subjects report to the testing facility for the conditioning phase of the study, which consists of using an assigned marketed personal washing cleanser for general use at home, up to four days prior to start of the product application phase. On Day 1 of the product application phase, a visual assessment is made to determine subject qualification. Subjects must have dryness scores ≤ 1.0 and erythema scores ≤ 0.5 , and be free of cuts and abrasions on or near the test sites to be included in the product application phase. Subjects who qualify to enter the product application phase will then be instructed to discontinue the use of the conditioning product and any other skin care products on their inner forearms, with the exception of the skin cleansing test formulations that are applied during the wash sessions.

Qualified subjects will then have four 3.0-cm diameter (round) evaluation sites marked on each of the forearms using a skin safe pen (a total of eight sites). Visual evaluations for erythema and dryness will be conducted immediately prior to the first wash in each session and again in the afternoon of the final day (Day 5).

Washing Procedure for Bar Products:

25

1. Both arms are washed simultaneously. Test sites are treated in a sequential manner starting with the site closest to the flex area, ending with the site proximal to the wrist.

- 31 -

2. The sites closest to the flex area of the inner forearm of both the right and left arm are moistened with warm water (90°-100°F).
3. A moistened Masslinn towel is rubbed in a circular motion on a wetted test bar for approximately 6 seconds by study personnel which will result in 0.2-0.5 g of product to be dispensed.
4. The site is washed with the designated product for 10 seconds followed by a 90-second lather retention phase.
5. The above procedure (1- 4) is then repeated for each of the test sites. Sites are then be rinsed for fifteen seconds and patted dry.
6. Upon completion the entire procedure is repeated (two washes/session).

15

For Liquid Products: A technician will prepare liquid products just prior to the wash session by dispensing between 0.1g and 0.5g of product either directly onto the skin or a moistened Maslinn towel or alternative application material.

20 The washing procedure outlined above will then be used.

Evaluation Methods

Baseline visual assessments are made prior to the start of the product application phase, and immediately before each wash session to evaluate dryness and erythema thereafter. The final visual evaluation is conducted on the afternoon of the final day. Washing of a test site will be discontinued if a clinical dryness or erythema score of \geq 4.0 is reached, or at the subject's request. If only one arm is discontinued, the remaining arm will continue to be

- 32 -

washed according to schedule. The same evaluator under conditions that are consistent throughout the study will conduct all of the visual evaluations. The 0-6 grading scale shown in Table 2 is used to assess the test sites for dryness and erythema. To maintain the evaluator's blindness to product assignment, visual assessments are conducted in a separate area away from the product application area.

TABLE 2

10

Grade	Erythema	<u>Dryness</u>
0	None	None
1.0	Barely perceptible redness	Patches of slight powderiness and occasional patches of small scales may be seen. Distribution generalized
2.0	Slight redness	Generalized slight powderiness. Early cracking or occasional small lifting scales may be present.
3.0	Moderate redness	Generalized moderate powderiness and/or heavy cracking and lifting scales.
4.0	Heavy or substantial redness	Generalized heavy powderiness and/or heavy cracking and lifting scales
5.0	Extreme redness	Generalized high cracking and lifting scales. Powderiness may be present but not prominent. May see bleeding cracks.
6.0	Severe redness	Generalized severe cracking. Bleeding cracks. Bleeding cracks may be present. Scales large, may be beginning to disappear.

- 33 -

Instrumental readings are taken on the first (baseline) and final day of the study.

A single Servo-Med Evaporimeter (TEWL) and three Skicon
5 measurements will be taken on each test site, at baseline
(prior to start of the first wash) and at the endpoint
session (three hours after the last wash on Friday, or three
hours after the wash where the subject receives a termination
grade of 4 or greater). Subjects must equilibrate in the
10 instrument room for a minimum of 30 minutes, exposing their
arms. Subjects with baseline TEWL measurements of > 10 ,
which may be indicative of barrier damage, are not included
in the product application phase of study.

15 Data Analysis

Within Test Product Effects

This protocol adopts as a working assumption the view
20 promulgated by Ertel et al (Ertel, K.D., G.H. Keswick, and P.B.
Bryant. *Forearm controlled application technique for
estimating the relative mildness of personal cleansing
products.*, J. Soc. Cosmet. Chem., 46, 67 (1995)) that the
dryness and erythema scales are linear. Hence, parametric
25 statistical methods will be used. The effects of each test
product will be examined by comparing the clinical grade at
each time point versus the baseline clinical grade using a
paired t-test. Statistical significance will be determined
at the 90% confidence level (p-value 0.10) to determine if
30 treatment results are statistically different from their
baseline score and in which direction. (G.W. Snedecor and

- 34 -

W.G. Cochran, *Statistical Methods*. Ames, Iowa. The Iowa State University Press, 1980, pp. 84-86).

Between Test Product Effects

5

For all treatments, differences will be statistically compared using an analysis of variance with panelist acting as a block to compare the extent of "change from baseline" among the treatments. Following the Ertel et al published
10 model approach, the fixed effects analysis of variance is intended to account for varying skin conditions along the volar forearm surface as well as side (left arm versus right arm) differences.

15 The general model is: response $ijklm = \mu + T_i + S_j + A_k$
+ $P_l + I_{jk} + \epsilon_{ijklm}$ where

μ = the grand mean
T = effect due to treatment i
S = effect due to treatment site j
20 A = effect due to the side (arm), k, on which the
treatment appears
P = effect due to subject l
I = a site * side interaction term
 ϵ = an error term that includes error due to the
25 various effects & experimental error, m.

with all effects other than error modeled as fixed effects.

30 If overall statistically significant differences are detected, pairwise treatment comparisons will be implemented

- 35 -

by comparing the least square means using either Fisher's Least Significant Difference test (LSD) or Dunnett's test (if comparing treatments to a common control). The least square means are more accurate estimators than the regular means in
5 that they adjust for other terms in the model and rectify slight imbalances which may sometimes occur due to missing data.

In addition, for each attribute, a survival analysis
10 will examine treatment performance over wash sessions. The analysis will incorporate the number of wash sessions that a subject's treatment site is actually washed in the study. If the treatment site is discontinued, then the site's survival time is determined at that evaluation. An overlay plot of
15 the estimated survival function for each treatment group will be examined. The Log-Rank test statistic will be computed to test for homogeneity of treatment groups. This test will tell if the survival functions are the same for each of the treatment groups.

20

2. Transepidermal Water Loss (TEWL)

The ServoMed Evaporimeter Model EP 1D, (ServoMed Inc, Broomall, PA) was used to quantify the rates of
25 transepidermal water loss following the procedures similar to those outlined by Murahata et al (*"The use of transepidermal water loss to measure and predict the irritation response to surfactants"* Int. J. Cos. Science 8, 225 (1986)). TEWL provides a quantitative measure of the integrity of the
30 stratum corneum barrier function and the relative effect of cleansers.

- 36 -

The operating principle of the instrument is based on Fick's law where

$$(1/A) (dm/dt) = -D (dp/dx)$$

5

where

A = area of the surface (m^2)

m = weight of transported water (g)

10

t = time (hr)

D = constant, 0.0877 g-lh⁻¹ (mm Hg)⁻¹ related to the diffusion coefficient of water

p = partial pressure of water vapor in air (mm Hg)

x = distance of the sensor from the skin surface (m)

15

The evaporation rate, dm/dt, is proportional to the partial pressure gradient, dp/dx. The evaporation rate can be determined by measuring the partial pressures at two points whose distance above the skin is different and known, and
20 where these points are within a range of 15-20 mm above the skin surface.

The general clinical requirements are as follows:

- 25 1. All panelists are equilibrated for a minimum of fifteen minutes before measurements in a test room in which the temperature is controlled to 21 +/- 1°C and 50 +/- 5% RH respectively.
2. The test sites are measured or marked in such a way
30 that pre and post treatment measurements can be taken at approximately the same place on the skin.

- 37 -

3. The probe is applied in such a way that the sensors are perpendicular to the test site, using a minimum of pressure.

5 Probe Calibration is achieved with a calibration set (No. 2110) which is supplied with the instrument. The kit must be housed in a thermo-insulated box to ensure an even temperature distribution around the instrument probe and calibration flask.

10

 The three salt solution used for calibration are LiCl, [MgNO₃]₂, and K₂SO₄. Pre-weighed amounts of salt at high purity are supplied with the kit instrument. The solution concentrations are such that the three solutions provide a RH
15 of ~11.2%, ~54.2%, and ~97% respectively at 21°C.

 General use of the instrument is as follows:

- 20 1. For normal studies, instrument readings are taken with the selector switch set for 1-100 g/m²h range
2. The protective cap is removed from the probe and the measuring head is placed so that the Teflon capsule is applied perpendicularly to the evaluation site ensuring that a minimum pressure is
25 applied from the probe head. To minimize deviations of the zero point, the probe head should be held by the attached rubber-insulating stopper.
3. Subject equilibration time prior to prior to evaluation is 15 minutes in a temperature/humidity
30 controlled room (21 +/- 1°C and 50 +/- 5% RH respectively).

- 38 -

4. The probe is allowed to stabilize at the test site for a minimum of 30 seconds before data acquisition. When air drafts exist and barrier damage is high it is recommended to increase the stabilization time.
5. Data is acquired during the 15 seconds period following the stabilization time.

3. Hydration

10

The Corneometer Skin Hygrometer (Diastron Ltd., Hampshire, England) is a device widely used in the cosmetic industry. It allows high frequency, alternating voltage electrical measurements of skin capacitance to be safely made via an electrode applied to the skin surface. The parameters measured have been found to vary with skin hydration. However, they may also vary with many other factors such as skin temperature, sweat gland activity, and the composition of any applied product. The Corneometer can only give directional changes in the water content of the upper stratum corneum under favorable circumstances but even here the quantitative interpretations may prove misleading.

A widely used alternative is the Skicon Skin conductance Meter (I.B.S. Co Ltd. Shizuoka-ken, Japan).

Panelist Requirements for either instrument are as follows:

1. Subjects should equilibrate to room conditions, which are maintained at a fixed temperature and

- 39 -

relative humidity (21+/- 1°C and 50 +/- 5% RH respectively) for a minimum of 15 minutes with their arms exposed. Air currents should be minimized.

2. Physical and psychological distractions should be minimized, e.g., talking and moving around.
3. Consumption during at least 1 hour before measurement of hot beverages or of any products containing caffeine should be avoided.
4. Panelists should avoid smoking for at least 30 minutes prior to measurements.

Operating Procedure

1. The probe should be lightly applied so as to cause minimum depression of the skin surface by the outer casing. The measuring surface is spring-loaded and thus the probe must be applied with sufficient pressure that the black cylinder disappears completely inside the outer casing.
2. The probe should be held perpendicular to the skin surface.
3. The operator should avoid contacting hairs on the measure site with the probe.
4. The probe should remain in contact with the skin until the instrument's signal beeper sounds (about 1 second) and then be removed. Subsequent measurements can be made immediately provided the probe surface is known to be clean.
5. A minimum of 3 individual measurements should be taken at separate points on the test area and

- 40 -

averaged to represent the mean hydration of the site.

6. A dry paper tissue should be used to clean the probe between readings.

5

4. Sensory Panel Evaluation

This evaluation protocol is used to differentiate the sensory properties of soap bars and employs a trained expert sensory panel. The methodology is a variant of that initially proposed Tragon and employs a language generation step.

The panel washes with each of up to a maximum of ten bars only once each, and will use the products up to a maximum of two per day. Each panelists washes their forearms using their normal habit for up to a maximum of 10 seconds, after which time they will rinse the product from their skin under running water. The panelists quantify various product attributes, using a line scale questionnaire, at various stages of the washing process. The key attributes evaluated include:

- a) Bar feel
- 25 b) Lather feel and appearance of hands during the initial lathering process
- c) Product/lather feel on the arm during washing
- d) Rinsability
- e) Wet skin feel after rinsing
- 30 f) Dry skin feel after 2 minutes

- 41 -

The water used was 40 PPM hardness expressed as PPM CaCO_3 .

EXAMPLES

5 The bar compositions were prepared as follows. Cooled soap noodles, PAG, and fatty acid, were charged to a Z blade mixer and mixed for 30 minutes at a temperature of 30°C. The remaining ingredients were added and mixed an additional 15 minutes. The mass was then transferred to a three roll mill, plodded into billets, cut and finally stamped into bars.

Example 1

15 The bar compositions shown in Table 3 were prepared.

TABLE 3

Ingredient	Composition Weight % in Bar	
	Bar 1 (Comparative)	Bar 2
Sodium soap 85% Tallow/15% Coconut Oil	86	76.5
Titanium Dioxide	0.3	0.3
EDTA	0.06	0.06
EHDP	0.04	0.04
White slurry*	0.4	0.4
Polyalkylene glycol Polyethylene glycol 600 (Mw = 600)		4.0
Coconut Fatty Acid	-	5.5
Perfume	0.7	0.7
Water	12.5	12.5

- 42 -

*White Slurry

	Water	97.32
	Sodium Tripolyphosphate	0.15
5	Sodium Carbonate	0.15
	Tinopol CBS (Optical Brightener)	2.38

10 Bar 1 and Bar 2 were evaluated in the Arm Wash
described above in the Methology Section.

15 The bars are compared in Table 4 and Figure 1 for their
ability to induce visual dryness as evaluated by an expert
grader. It is clear that the inclusion of PAG in the soap
bar composition in defined ratios has significantly reduced
the drying potential of the soap bar.

20 The effects of PAG on the transepidermal water loss and
hydration level of the skin are summarized in Table 5. The
results demonstrate that the inclusion of the combination of
polyethylene glycol 600 and fatty acid into the soap bar
compositions reduces its potential to damage the skins
barrier function (TEWL) and to lower the skins ability to
25 hold water (increases hydration). The differences are
highly significant.

- 43 -

Table 4. Comparison Bar 1 and Bar 2 in Visual Dryness as a
Function of Time

		<u>Visual Dryness</u>						<u>LAST ASSESSMENT</u>
		<u>DAY 1</u>	<u>DAY 2</u>	<u>DAY 3</u>	<u>DAY 4</u>	<u>DAY 5</u>	<u>CUMUL</u>	
5	Bar 2	1.26	2.06	2.67	3.39	5.06	13.65	1.66
10	Bar 1	1.84	2.59	3.93	4.71	7.16	19.04	1.96
Sig. Diff		0.36	0.51	0.49	0.63	0.84	1.42	0.17
p=0.05								
15	p Value	0.0041	0.0429	0.0001	0.0004	0.0001	0.0001	0.0026

Table 5. Instrumental Assessment of Bar 1 and Bar 2
(Contains PAG/FA)

	Transepidermal Water Loss (Evaporimeter gm/M ² /hr)		Hydration estimated by Corneometer (a.u.)	
	Baseline	End Test	Baseline	End of test
Bar 1	2.80	16.04	73.8	44.9
Bar 2	2.65	12.14	75.0	49.8
Difference (Bar 2-Bar 1)	-0.15	- 3.9	1.2	+4.9
P value	0.33	0.03	0.2	0.008

- 44 -

This table clearly shows reduced transepidermal water loss of bar 2 versus bar 1 (12.14 versus 16.04) and, conversely, enhanced hydration (49.8 versus 44.9).

5 Example 2

The Bar compositions 3-6 shown in Table 6 were prepared.

10 Table 6. Bar Composition Prepared for Example 2.

Ingredient	Composition			
	Weight % in Bar			
	Bar 3	Bar 4	Bar 5	Bar 6
Sodium soap 85% Tallow/15% Coconut Oil	86.5	72.5		
Sodium soap 65%Palm Stearin/35% Coconut Oil			86.5	72.5
Titanium Dioxide	0.46	0.46	0.46	0.46
EDTA	0.02	0.02	0.02	0.02
EHDP	0.02	0.02	0.02	0.02
Polyalkylene glycol Poethylene glycol 600 (Mw = 600)		5.0		5.0
Fatty Acid Blend (C12, C14, C16, C18)		6.5		6.5
Sodium Citrate		2.5		2.5
Perfume	1.0	1.0	1.0	1.0
Water	12.0	12.0	12.0	12.0

- 45 -

These bar compositions were evaluated by the 4-site arm wash protocol described in the Methodology Section. The results are summarized in Table 7A and 7B. It is clear that the inclusion of PAG and FA (Bars 4 and 6) in either of the soap bar composition in the ratios defined herein significantly reduced the drying potential of these soap bars: Compare Bar 4 with Bar 3 (Table 7A) and Bar 6 with Bar 5 (Table 7B). The results are shown graphically in Figures 2 and 3.

The effects of PAG/FA on the transepidermal water loss and hydration level of the skin are summarized are also summarized in Table 5. The results demonstrate that the inclusion of the combination of polyethylene glycol 600 and fatty acid into the soap bar compositions reduces its potential to damage the skins barrier function (TEWL) and to increase the skins ability to hold water (increases hydration).

Table 7A. 4 sight arm wash results Bar 3 Vs Bar 4

<u>Product</u>	Dryness Change from baseline	TEWL	Skicon
Bar 3	0.78	4.14	-126.53
Bar 4	0.64	3.55	-89.09
Conclusion	Significant	Significant	Significant
p-value	0.0033	0.0583	0.0171

- 46 -

Table 7B. 4 sight arm wash results Bar 5 Vs Bar 6

<u>Product</u>	<u>Dryness Change from Baseline</u>	<u>TEWL</u>	<u>Skicon</u>
Bar 5	0.78	3.53	-144.8
Bar 6	0.64	3.55	-118.96
Conclusion	Significant	Not Significant	Significant
p-value	0.0042	0.500	0.0616

Example 3

5

The bar compositions shown in Table 8 were prepared. These bars were evaluated for their ability to induce dryness utilizing the FCAT protocol described in the Methodology Section.

10

Table 8. Bar composition prepared for Example 3.

<u>Ingredient</u>	<u>Composition Weight % in Bar</u>			
	<u>Bar 7</u>	<u>Bar 8</u>	<u>Bar 9</u>	<u>Bar 10</u>
Sodium soap 85% Tallow/15% Coconut Oil	86.5	56	56	56
Talc		32	12	15
Titanium Dioxide	0.46			
EDTA	0.02			
EHDP	0.02			
Polyalkylene glycol Polyethylene glycol 8000 Mw = 8000)			12	9
Coco amidopropyl betaine				2
Fatty Acid Blend (C12, C14)			8	6
Sodium Citrate				
Perfume	1.0			
Water	12	12	12	12

- 47 -

The results of instrumental assessments at the end-point are shown in Table 9. The inclusion of PAG and Fatty acid in Bar 9 and Bar 10 significantly reduces ($P < 0.05$) damage to the barrier function of the skin as demonstrated by lower rate transepidermal (1.54 and 2.03) water loss following treatment than with Bar 7 or Bar 8. It is also clear from the Skicon measurements that skin washed with either Bar 9 or Bar 10 which both contain PAG and fatty acid retain a higher level of water following than skin washed with the ordinary soap compositions (Bar 7 and Bar 8).

Table 9. Instrumental results at end-point following the FCAT protocol: Bars 7-10

	Bar 7	Bar 8	Bar 9	Bar 10
TEWL Change from Baseline (Evaporimeter gm/M ² /hr)	2.85	3.28	1.54	2.03
Hydration estimated from Skicon (arbitrary units)	-98.9	-87.4	-54.5	-44.8

Thus in three different wash protocol, the benefits of PAG in combination with fatty acid are evident.

Example 4

This example illustrates an important aspect of cleansing method of the current invention. Namely, that the inclusion of PAG and FA provides improved skin care without

- 48 -

reducing the clean and refreshing experience of washing with soap that is preferred by many consumers.

The bar compositions identified in Table 10 were prepared by the procedure that are described in Bar Preparation section.

Table 10. Bar compositions used in consumer testing for Example 4

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Composition	Bar 11	Bar 12	Bar 13	Bar 14	Bar 15
Sodium soap: ratio Tallow/coconut Oil	85/15	85/15	10/90	85/15	85/15
Anhydrous Sodium Soap	74.19	82.77	71.11	72.32	74.30
Sodium Citrate			2.0		
Titanium Dioxide	0.4	0.4	0.4	0.4	0.4
EDTA	0.04	0.04	0.04	0.03	0.04
EHDP	0.02	0.02	0.02	0.02	0.02
Polyalkylene glycol Polyethylene glycol 600 (Mw = 600)	4.00				
Paraffin Wax					10.0
Glycerol			9.30	6.13	
Fatty Acid Blend via Citric Acid			5.25		
Coconut Fatty Acid (added)	5.50			0.50	
Perfume	1.50	1.50	1.50	1.50	1.50
Water	13.00	13.50	10.00	17.50	12.5
Minors, Ingredients up to	100	100	100	100	100

Bars 11-15 were evaluated in two consumer panels. One panel had self-perceived oily skin while the other had self

- 49 -

perceived dry skin (200 consumers in each group). Bar 11 and 12 were preferred on lather and rinsing properties among oily skin consumers. Bar 11 was preferred overall by consumers who had dry skin for leaving the skin more moisturized.

Thus the method of cleansing with a soap bar incorporating PAG and fatty acid in the desired ratios is preferred by oily skin consumers for its cleansing properties. Simultaneously, this method is also preferred by dry skin consumers for its better skin care properties

Example 5

This example illustrates the importance of the ratio of fatty acid and polyalkylene glycol in achieving bars that can be manufactured economically and have good in-use properties. A series of soap bars compositions were prepared that incorporated different levels of fatty acid PAG in various ratios. All bars contained either a blend of ether 85/15 or 80/20 stearic (e.g., from tallow) to lauric (e.g., from coconut oil) soaps. The moisture content ranged from 10% to 16% with a center point at 13% which considered the standard. The bars fell into three classes depending on the FA/PAG ratio. When the FA/PAG ratio was too low the bars lacked sufficient cohesion and tended to crumble easily: "crumbly". When the FA/PAG ratio was too high, the bars were too sticky to be properly extruded and stamped at the process temperature: "sticky". In between these limits the compositions were processible.

- 50 -

The critical FA/PAG ratios at these limits are summarized in Table 11. The critical FA/PAG range varies somewhat with water content but is about 0.5 to about 2.0, i.e., in a ratio of 1:2 to 2:1.

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Table 11. Bar Composition Prepared for Example 2.

Moisture	Lower Fatty Acid/PAG Ratio (Crumbly Bars)	Upper Fatty acid/PAG Ratio (Sticky Bars)
13%	0	5
13%	0.2	3
13%	0.3	2.3
13%	0.42	2
13%	0.5	
13%	0.55	
13%	0.6	
10%	0	6
10%	0.25	3.5
10%	0.4	2.7
10%	0.5	2.25
10%	0.57	2
10%	0.62	
10%	0.66	
10%	0.7	
16%	0	3
16%	0.16	2
16%	0.17	1.66
16%	0.28	1.25
16%	0.37	1
16%	0.55	1

- 51 -

Example 6

Table 12 illustrates bar compositions relevant to the instant invention

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Table 12. Examples of Relevant Bar Compositions

Ingredient	Composition Weight % in Bar					
	Bar 16	Bar 17	Bar 18	Bar 19	Bar 20	Bar 21
Sodium soap 85% Tallow/15% Coconut Oil	69.9	66.6	64.1			
Sodium soap 65% Palm Stearin/35% Coconut Oil				75.0	67.6	58.4
Titanium Dioxide	0.36	0.36	0.36	0.36	0.36	0.36
EDTA	0.02	0.02	0.02	0.02	0.02	0.02
EHDP	0.02	0.02	0.02	0.02	0.02	0.02
Polyalkylene glycol Polyethylene glycol 8000 (Mw = 8000)	4	2	5	4	3	6
Sunflower seed oil	4	2	2	2	3	
Vitamin C acetate	.2			0.1		0.2
Calcium Carbonate		5				4
Talc			4		4	
Coco amidopropyl betaine						2
Fatty Acid Blend (C12, C14)	5.5				5	6
Fatty acid Blend (C10-C18)		4	6	5.5		5
Sodium cocoyl isethionate			2			1
Petrolatum		2	2		2	2
Silicone oil (60,000 cst)	2	2			1	1
Sodium Citrate		2	2.5	2.0		3
Perfume	1.0	1.0	1.0	1.0	1.0	1.0
Water	13	13	11	10	13	10

Example 7.

Table 13 further illustrates bar compositions useful in practicing the instant invention.

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Table 13. Examples of Relevant Bar Compositions for Example 7

Ingredient	Composition Weight % in Bar								
	Bar 22	Bar 23	Bar 24	Bar 25	Bar 26	Bar 27	Bar 28	Bar 29	Bar 30
Sodium soap 85% Tallow/15% Coconut Oil	73.3	61.1	71.6		71.5		79.4		59.5
Sodium soap 65%Palm Stearin/35% Coconut Oil				75.2		69.9		73.9	
Titanium Dioxide	0.36	0.36	0.36	0.36	0.36	0.36	0.36	0.36	0.36
EDTA	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
EHDP	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Polyalkylene glycol Polyethylene glycol 10,000 (Mw = 10000)		8			4				10
Polyalkylene glycol Polyethylene glycol 600 (Mw =600)	4		5	4		6	4.5	5	
Sunflower seed oil		2						2	2
Vitamin E	0.2		0.1	0.1		0.2		0.1	
Niacinamide							1.0		
Sea weed extract			0.5	0.5					
Triclocarban (antimicrobial)					1.4				
Irgasan DP 300 (antimicrobial)			0.3	0.2	0.2				
Vitamin C	0.1		0.1	0.1				0.1	
Parcol MCX (Sunscreen)									1
Sodium Citrate (tribasic)		2.5	2.5	2					3
Sodium Lactate							2.7	2.5	
Sodium adipate	2.5				2.5				
Jaguar 13 S (Cationic polymer)		1				2.5			1
Fatty acid Blend (C10-C18)	5.5	6	5.5	5.5	5.5	7			8
Sodium cocoyl isethionate		2							
Petrolatum		2						2	1.6
Silicone oil (60,000 cst)		1					1		1.5
Perfume	1.0	1.0	1.0	1	1.5	1	1.0	1.0	1.0
Water	13	13	13	11	13	13	10	13	11

Example 8

This example further illustrates the influence of PAG in improving the skin condition performance of soap bar. The bar compositions shown in Table 14 were prepared. These bars were evaluated for their ability to induce dryness utilizing the FCAT protocol described in the Methodology Section.

Table 14. Bar Composition Prepared for Example 8

Ingredient	Composition	
	Weight % in Bar	
	Bar 31	Bar 32
Sodium soap 85% Tallow/15% Coconut Oil	86.5	72.3
Dimethicone		1.0
Free fatty acid		4.0
EDTA		0.02
EHDP		0.04
Polyalkylene glycol Polyethylene glycol 600 (Mw = 600)		4.0
Titanium dioxide		0.4
Fatty Acid Blend (C12, C14)		
Sodium Chloride		
Sodium Citrate	0.5	1.5
Tinopal CBS		0.024
Perfume		1.27
Glycerin, sodium chloride		<1.5
Water	13.0	14.0

- 54 -

The results of Skicom instrumental assessments at the end-point are shown in Table 15. It is also clear from the Skicon measurements that skin washed with Bar 32 that contained 4% PAG retains a higher level of water than skin washed with the ordinary soap compositions, Bar 31.

Table 15. Instrumental Results at End-Point Following the FCAT Protocol:

Change in Skicom from Baseline	Bar 31	Bar 32
Hydration estimated from Skicon (arbitrary units)	-18.24	-36.36

As can be clearly seen, Bar 32 (with greater conductivity) is far superior to Bar 31.

- 55 -

CLAIMS

1. A method of cleansing the skin that provides effective cleansing and improved skin care relative to cleansing with
5 ordinary soap comprising washing the skin with an effective amount of water and a bar containing:

- i) from 25 to 87% of a fatty acid soap;
- 10 ii) a polyalkylene glycol having a molecular weight of from 400 to 25,000 Dalton;
- iii) C₈ to C₂₀ saturated or unsaturated fatty acid or mixtures thereof.

15 wherein the amount of polyalkylene glycol present in the bar must be sufficient to improve skin condition in Controlled Application Wash Tests either by reducing the barrier damage as measured by transepidermal water loss, increasing skin hydration as measured by skin conductivity/capacitance, and/or by reducing visual
20 dryness,
wherein the fatty acid (iii) and polyethylene glycol (ii) are present in a ratio of from 1:2 to 2:1.

2. Method of claim 1 where the polyalkylene glycol has a
25 molecular weight between 400 and 8000 and is present at a level of 1.5% to 25% by weight.

3. Method of claim 1 where the fatty acid component is C₁₀-
30 C₁₈ and is present at a level between 1 and 14% by weight.

- 56 -

4. Method of claim 1 where the fatty acid is C₁₀-C₁₈ saturated or unsaturated fatty acid and is present at 2 to 14%; and wherein the polyalkylene is polyethylene glycol of MW between 400 and 8000 and is present at 1.5 to 25% by weight.
5. Method of claim 1 wherein the bar composition comprises:
- (a) 65-80 wt.% fatty acid soap consisting of a blend of fatty acid soaps derived from non-lauric fats/oils and lauric fats/oils blended in a ratio of from 95/5 to 50/50;
 - (b) 2-6 wt.% of a polyethylene glycol of molecular weight 400-8000;
 - (c) 3-8 wt.% of C₁₂-C₁₈ fatty acids;
 - (d) 0-3 wt.% of sodium citrate.
6. A method of claim 5 wherein the bar composition also contains from 0.1 to 10 wt.% of moisturizing benefit agent selected from the group consisting of sunflower seed oil, soy bean oil, borage seed oil, primrose oil, essential fatty acids, petrolatum, mineral oil, vitamin A, E and C, glycerol, linoleic acid, salts of lactic acid and pyrrolidone carboxylic acid, amino acids and proteins, and mixtures thereof.
7. A method of claim 5, wherein the bar composition also contains from 0.1 to 10 wt.% of benefit agent useful for the treatment of oily skin selected from the group consisting of minerals, clays, plant extracts, sea/algae extracts, vitamins, silica, alpha and beta

- 57 -

hydroxy acids, inorganic silica, talc and mixtures thereof.

- 5 8. A method according to claim 7, wherein alpha and beta hydroxy acids are selected from group consisting of lactic acid, citric acid, glycolic acid, salicylic acid and mixtures thereof.
- 10 9. A method of claim 5, wherein the bar composition also contains from 0.1 to 10 wt.% of skin renewal benefit agent selected from the group consisting of ceramides and pseudoceramides, niacin amide, vitamin C and its derivatives, and mixtures thereof.
- 15 10. A method of claim 5, wherein the bar composition also contains from 0.1 to 5 wt.% of an antimicrobial agent selected from the group consisting of triclosan, trichlorocarban, tea tree oil, zinc salts and mixtures thereof.
- 20 11. A method of claim 1 where the bar composition also contains from 0.5 - 10 wt % of an auxiliary surfactant selected from the group consisting of acyl isethionates, alcohol ethoxylates, fatty acid esters of polyethylene glycol, alkene sulfonates, alkyl betaines, and alkyl amido propyl betaines.
- 25

Figure 1. Comparison Bar 1 and Bar 2 in Induction of Visual Dryness.

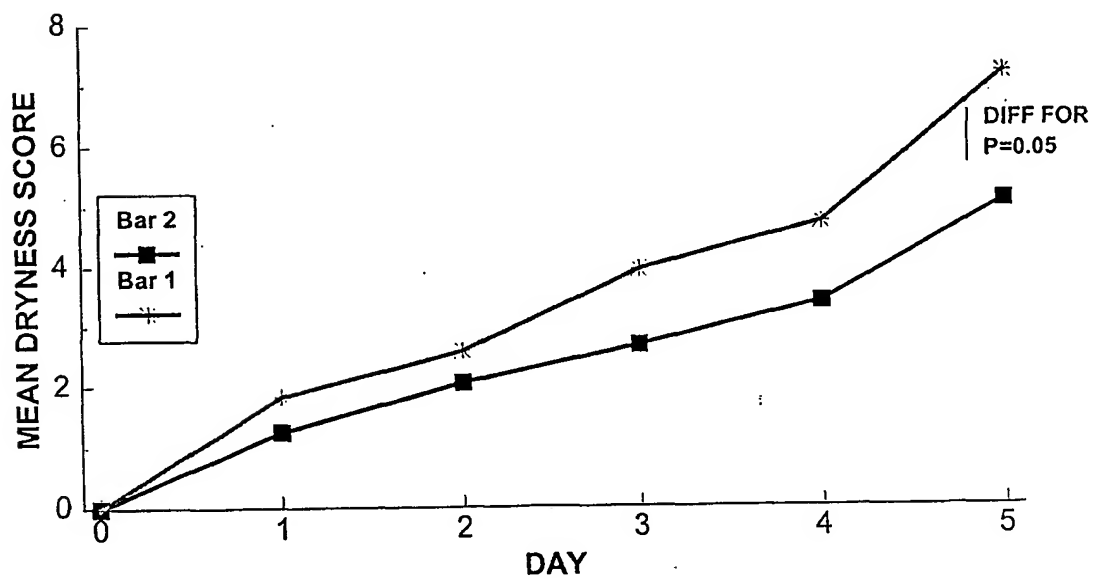


Figure 2. Comparison Bar 3 and Bar 4 in induction of visual dryness.

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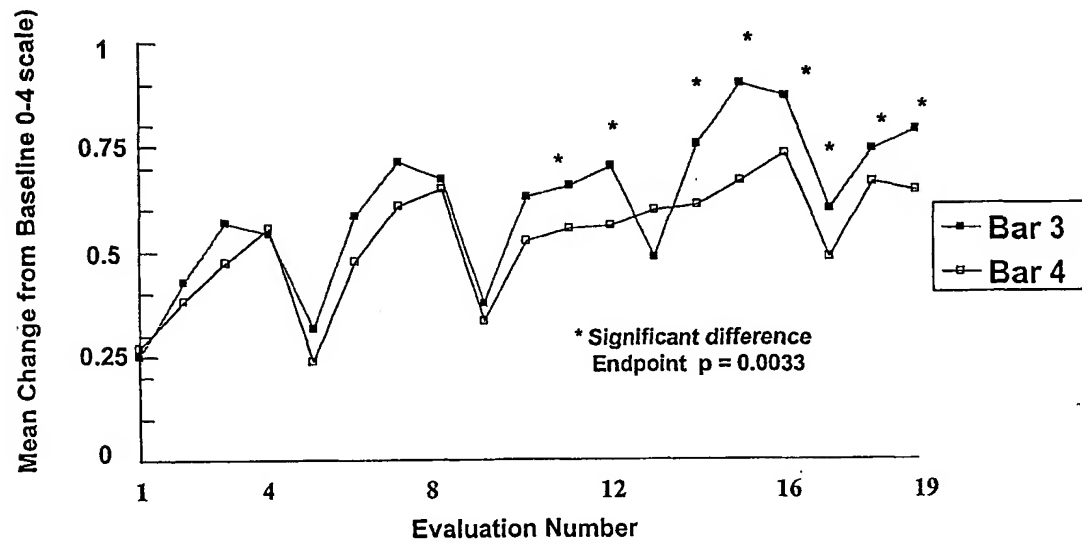
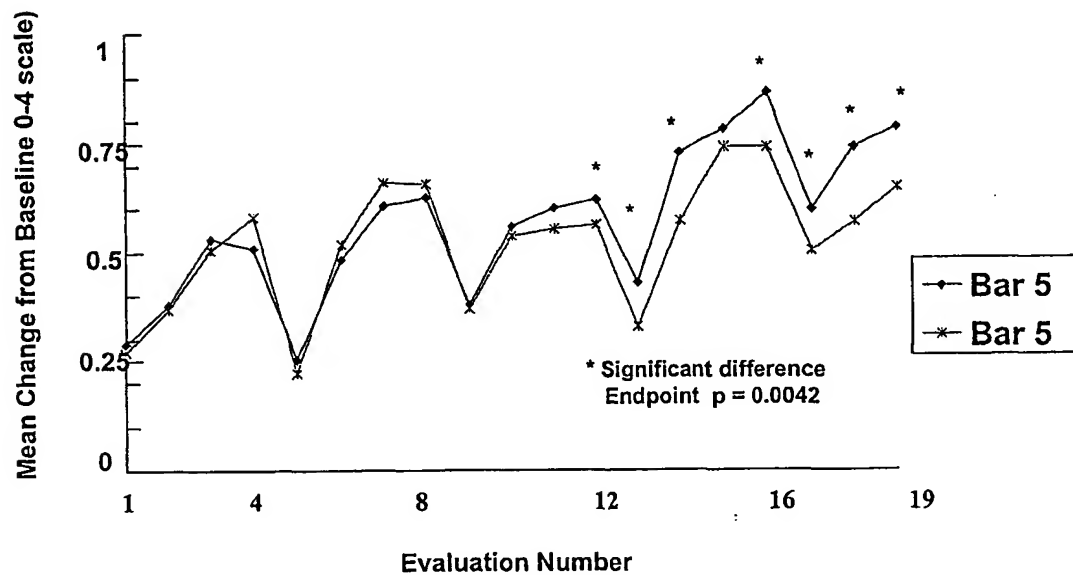


Figure 3. Comparison Bar 5 and Bar 6 in induction of visual dryness.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **METHOD OF CLEANSING SKIN AND IMPROVING SKIN CARE IN BAR COMPRISING SOAP, FATTY ACID AND POLYALKYLENE GLYCOL**

(57) Abstract: The invention discloses a method for cleansing skin comprising washing with bars comprising predominantly fatty acid soap; free fatty acid and polyalkylene glycol wherein fatty acid to PAG are present in defined ratio and where skin condition is improved as measured by reduced skin damage as further measured by at least one of two defined tests.

INTERNATIONAL SEARCH REPORT

International Application No

PC1/EP 01/03838

A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

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IPC 7 C11D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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